

IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF NEW YORK

PURDUE PHARMA L.P.,  
THE P.F. LABORATORIES, INC.,  
PURDUE PHARMACEUTICALS L.P.,  
and RHODES TECHNOLOGIES,

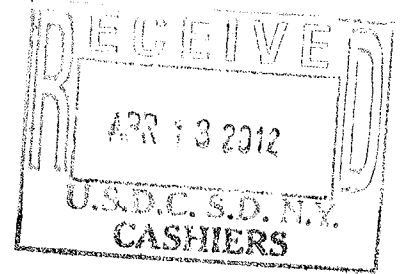
Plaintiffs,

v.

MYLAN PHARMACEUTICALS INC.  
and MYLAN INC.,

Defendants.

12 CV 2959  
C.A. No. \_\_\_\_\_



**PLAINTIFFS PURDUE PHARMA L.P., THE P.F. LABORATORIES, INC.,  
PURDUE PHARMACEUTICALS L.P., AND RHODES TECHNOLOGIES'  
STATEMENT OF RELATED CASES UNDER LOCAL RULE 1.6**

Pursuant to Rule 1.6 of the Local Rules of the U.S. District Court for the Southern District of New York, Plaintiffs Purdue Pharma L.P., The P.F. Laboratories, Inc., Purdue Pharmaceuticals L.P., and Rhodes Technologies ("Purdue") set forth the following facts.

This is an action for relief from patent infringement. The three U.S. patents at issue are listed in the U.S. Food and Drug Administration's ("FDA") "Orange Book" (*Approved Drug Products With Therapeutic Equivalence Evaluation*) as covering OxyContin<sup>®</sup> Tablets, a controlled-release oral dosage form of the pain medication oxycodone hydrochloride. The accused infringer in this action has filed an Abbreviated New Drug Application ("ANDA") seeking FDA approval to make a generic copy of OxyContin<sup>®</sup> before the expiration of the patents in suit.

The Hon. Sidney H. Stein has previously presided or is presiding over eleven actions for patent infringement of patents relating to Purdue's original OxyContin<sup>®</sup> formulation, the formulation of OxyContin<sup>®</sup> based on Purdue's 1994 New Drug Application No. 20-553 (as amended and/or supplemented). These actions, along with an action filed on April 10, 2012 that has yet to be assigned, are identified on Schedule A. Of the twelve "Schedule A" actions, eleven were based on ANDA filings.<sup>1</sup> Three such patent infringement actions are still pending, the *Ranbaxy et al.* action, the 2010 *Varam* action, and the 2012 *Varam* action.<sup>2</sup>

In addition to the above-mentioned patent infringement actions, Judge Stein also presides over a multidistrict litigation titled *In re OxyContin Antitrust Litigation*, 04-md-1603 (SHS). The pending *Ranbaxy et al.* and 2010 *Varam* actions are associated with this multidistrict litigation.

The three patents at issue in the present action are also at issue in the pending *Ranbaxy et al.* and *Varam* actions.<sup>3</sup> These patents relate to an improved active ingredient having lower levels of a particular impurity (the "Low ABUG" patents).

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<sup>1</sup> In the *Boehringer* case, the defendants contended that their formulation was, in fact, a new drug, not a copy of OxyContin<sup>®</sup>. Purdue contended that, under controlling law, the *Boehringer* formulation should have been treated as a "505(b)(2)" application, which would trigger notice and stay provisions similar to an ANDA. See 21 U.S.C. § 355(b)(2); *Purdue Pharma L.P. v. Boehringer Ingelheim GmbH*, 99 Civ. 3658 (SHS) (D.I. 118 Stipulation and Order to Stay Proceedings).

<sup>2</sup> *Purdue Pharma L.P. et al. v. Ranbaxy Inc. et al.*, No. 10-civ-3734 (SHS) (the "pending *Ranbaxy et al.*" action), *Purdue Pharma L.P. et al. v. Varam, Inc. et al.*, Nos. 10-civ-6038, 11-civ-0766 (SHS) (the "2010 *Varam*" action) and *Purdue Pharma L.P. et al. v. Varam, Inc. et al.*, No. 12-civ-2814 (S.D.N.Y. Apr. 10, 2012) (the "2012 *Varam*" action).

<sup>3</sup> These three patents are U.S. Patent No. 7,674,799, No. 7,674,800, and No. 7,683,072. The *Varam* actions also involve a fourth patent, U.S. Patent No. 5,508,042 ("the '042 patent"), one of the patents in suit in the earlier actions identified on Schedule A.

Purdue has reformulated OxyContin<sup>®</sup> in an effort to make the tablet more difficult to manipulate for the purpose of intentional misuse and abuse, and submitted a New Drug Application, NDA No. 022272, on reformulated OxyContin<sup>®</sup> to the FDA. Purdue's NDA No. 022272 was approved in April 2010. Purdue began selling its reformulated product in August 2010.

Since March 23, 2011, a total of nine actions have been filed in this Court against defendants seeking FDA approval to make a generic copy of reformulated OxyContin<sup>®</sup>. The patents at issue in five of these actions include the same patents at issue in this action: the three Low ABUK patents and two additional patents: U.S. Patent No. 6,488,963, titled "Hot-Melt Extrudable Pharmaceutical Formulation" and U.S. Patent No. 7,776,314, titled "Abuse-Proofed Dosage System." The three Low ABUK patents and U.S. Patent No. 7,776,314 are at issue in the actions against Teva Pharmaceuticals USA, Inc. and Amneal Pharmaceuticals, LLC.

Purdue previously commenced suit on May 5, 2010 against Mylan Pharmaceuticals, Inc. and Mylan, Inc. (collectively "Mylan") for seeking approval to make a generic copy of original OxyContin<sup>®</sup>. This is the pending *Ranbaxy et al.* action. That suit was based on a separate ANDA No. 200692 that Mylan previously submitted to the FDA based on Purdue's previous OxyContin<sup>®</sup> NDA No. 20-553. The present suit relates to Mylan's new ANDA No. 203915, and the reference listed drug is Purdue's reformulated OxyContin<sup>®</sup>.

In addition, Purdue commenced suit against Ranbaxy Inc., Ranbaxy Pharmaceuticals Inc., and Ranbaxy Laboratories Ltd. on April 8, 2011 (for 30 mg, 40 mg, 60 mg, and 80 mg dosage strengths) and on October 7, 2011 (for 10 mg, 15 mg, and 20 mg dosage

strengths), which also seek approval to make a generic copy of reformulated OxyContin<sup>®</sup>. In these suits, only the three Low ABUK patents are at issue.<sup>4</sup>

The previously filed actions relating to reformulated OxyContin<sup>®</sup> are assigned to Judge Stein. These actions, plus the present action, are identified on Schedule B.

Dated: April 13, 2012

ROPES & GRAY LLP



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<sup>4</sup> On December 27, 2011, this Court consolidated the 2011 actions against Ranbaxy, relating to reformulated OxyContin<sup>®</sup>, with the 2010 action against Ranbaxy, relating to the original OxyContin<sup>®</sup> formulation.

**SCHEDULE A: ACTIONS RELATING TO THE ORIGINAL OXYCONTIN<sup>®</sup>  
FORMULATION**

- *Purdue Pharma L.P., The Purdue Frederick Company, The P.F. Laboratories, Inc., and The Purdue Pharma Company v. Boehringer Ingelheim GmbH, Roxane Laboratories, Inc., and Boehringer Ingelheim Corporation*, 99 Civ. 3658 (SHS) (the “Boehringer action”).
- *Purdue Pharma L.P., The Purdue Frederick Company, The P.F. Laboratories, Inc., and The Purdue Pharma Company v. Endo Pharmaceuticals Inc. and Endo Pharmaceuticals Holdings Inc.*, 00 Civ. 8029, 01 Civ. 2109, 01 Civ. 8177 (SHS) (the “Endo actions”).
- *Purdue Pharma L.P., The Purdue Frederick Company, The P.F. Laboratories, Inc., and The Purdue Pharma Company v. Teva Pharmaceuticals USA, Inc.*, 01 Civ. 8507, 01 Civ. 11212, 03 Civ. 2312 (SHS) (the “Teva actions”).
- *Purdue Pharma L.P., The Purdue Frederick Company, The P.F. Laboratories, Inc., and The Purdue Pharma Company v. Impax Laboratories, Inc.*, 02 Civ. 2803, 02 Civ. 7569, 02 Civ. 8036 (SHS) (the “Impax actions”).
- *Purdue Pharma L.P., The P.F. Laboratories, Inc. and Purdue Pharmaceuticals L.P. v. Mallinckrodt Inc.*, 06 Civ. 13095 (SHS) (the “Mallinckrodt action”).
- *Purdue Pharma L.P., The P.F. Laboratories, Inc. and Purdue Pharmaceuticals L.P. v. KV Pharmaceutical Company and Actavis Totowa LLC*, 07 Civ. 3972 (SHS) (the “KV/Actavis action”).
- *Purdue Pharma L.P., The P.F. Laboratories, Inc. and Purdue Pharmaceuticals L.P. v. KV Pharmaceutical Company*, 07 Civ. 3973, 07 Civ. 4810 (SHS) (the “other KV actions”).
- *Purdue Pharma L.P., The P.F. Laboratories, Inc. and Purdue Pharmaceuticals L.P. v. Apotex Inc. and Apotex Corp.*, 07 Civ. 8002 (SHS) (the “Apotex action”).
- *Purdue Pharma L.P., The P.F. Laboratories, Inc. and Purdue Pharmaceuticals L.P. v. Ranbaxy Inc., Ranbaxy Pharmaceuticals Inc., and Ranbaxy Laboratories Ltd.*, 09 Civ. 8878 (SHS) (the “prior Ranbaxy action”).
- *Purdue Pharma L.P., The P.F. Laboratories, Inc., Purdue Pharmaceuticals L.P. and Rhodes Technologies v. Ranbaxy Inc., Ranbaxy Pharmaceuticals Inc., Ranbaxy Laboratories Ltd., Mylan, Inc., Mylan Pharmaceuticals, Inc. and Actavis Elizabeth LLC*, 10 Civ. 3734 (SHS) (the “pending Ranbaxy et al. action”).
- *Purdue Pharma L.P., The P.F. Laboratories, Inc., Purdue Pharmaceuticals L.P. and Rhodes Technologies v. Varam, Inc. & KVK-Tech, Inc.*, 10 Civ. 6038, 11 Civ. 0766 (SHS) (the “2010 Varam” action).
- *Purdue Pharma L.P., The P.F. Laboratories, Inc., Purdue Pharmaceuticals L.P. and Rhodes Technologies v. Varam, Inc. & KVK-Tech, Inc.*, 12 Civ. 2814 (S.D.N.Y. Apr. 10, 2012) (the “2012 Varam” action”).

**SCHEDULE B: ACTIONS RELATING TO THE OXYCONTIN<sup>®</sup> FORMULATION  
COVERED BY NDA 022272**

- *Purdue Pharma L.P., The P.F. Laboratories, Inc., Purdue Pharmaceuticals L.P., Rhodes Technologies, Board of Regents of the University of Texas System, and Grünenthal GmbH v. Watson Laboratories, Inc. – Florida and Andrx Labs, LLC*, No. 11 Civ. 2036 (SHS) (S.D.N.Y. Mar. 23, 2011).
- *Purdue Pharma L.P., The P.F. Laboratories, Inc., Purdue Pharmaceuticals L.P., Rhodes Technologies, and Grünenthal GmbH v. Teva Pharmaceuticals USA, Inc.*, No. 11 Civ. 2037 (SHS) (S.D.N.Y. Mar. 23, 2011).
- *Purdue Pharma L.P., The P.F. Laboratories, Inc., Purdue Pharmaceuticals L.P., Rhodes Technologies, Board of Regents of the University of Texas System, and Grünenthal GmbH v. Actavis Elizabeth LLC*, No. 11 Civ. 2038 (SHS) (S.D.N.Y. Mar. 23, 2011).
- *Purdue Pharma L.P., The P.F. Laboratories, Inc., Purdue Pharmaceuticals L.P., Rhodes Technologies, Board of Regents of the University of Texas System, and Grünenthal GmbH v. Impax Laboratories, Inc.*, No. 11 Civ. 2400 (SHS) (S.D.N.Y. Apr. 8, 2011).
- *Purdue Pharma L.P., The P.F. Laboratories, Inc., Purdue Pharmaceuticals L.P., and Rhodes Technologies v. Ranbaxy Inc., Ranbaxy Pharmaceuticals Inc., and Ranbaxy Laboratories Ltd.*, No. 11 Civ. 2401 (SHS) (S.D.N.Y. Apr. 8, 2011) (consolidated with *Purdue v. Ranbaxy et al.*, 10 Civ. 3734 (SHS) (cited on Schedule A)).
- *Purdue Pharma L.P., The P.F. Laboratories, Inc., Purdue Pharmaceuticals L.P., Rhodes Technologies, Board of Regents of the University of Texas System, and Grünenthal GmbH v. Sandoz Inc.*, No. 11 Civ. 4694 (SHS) (S.D.N.Y. July 7, 2011).
- *Purdue Pharma L.P., The P.F. Laboratories, Inc., Purdue Pharmaceuticals L.P., and Rhodes Technologies v. Ranbaxy Inc., Ranbaxy Pharmaceuticals Inc., and Ranbaxy Laboratories Ltd.*, No. 11 Civ. 7104 (SHS) (S.D.N.Y. Oct. 7, 2011) (consolidated with *Purdue v. Ranbaxy et al.*, 10 Civ. 3734 (SHS) (cited on Schedule A)).
- *Purdue Pharma L.P., The P.F. Laboratories, Inc., Purdue Pharmaceuticals L.P., Rhodes Technologies, and Grünenthal GmbH v. Amneal Pharmaceuticals, LLC*, No. 11 Civ. 8153 (SHS) (S.D.N.Y. Nov. 10, 2011).
- *Purdue Pharma L.P., The P.F. Laboratories, Inc., Purdue Pharmaceuticals L.P., Rhodes Technologies, Board of Regents of the University of Texas System, and Grünenthal GmbH v. Sandoz Inc.*, No. 12 Civ. 0897 (SHS) (S.D.N.Y. Feb. 3, 2012).
- *Purdue Pharma L.P., The P.F. Laboratories, Inc., Purdue Pharmaceuticals L.P. and Rhodes Technologies v. Mylan Pharmaceuticals, Inc. and Mylan, Inc.*, 12 Civ. \_\_\_\_ (S.D.N.Y. Apr. 13, 2012).